OCT - 2 2000

510(k) Summary
Ceralas G15 Laser System K002296

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
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Contact Person: Carol Morello, V.M.D.
Date prepared: June 20, 2000

Name of Device and Name/Address of Sponsor

Ceralas G15 Laser System (Models G1-G15)
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical laser

Predicate Device

Ceralas G Laser System (Models G2 and G3)
Laserscope Aura/Lyra (KTP/532) Laser Systems Series
Cosmos Medical Technology COMPACT KTP Laser

Intended Use

The Ceralas G15 Laser System that is the subject of this 510(k) notice is intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included such as skin, cutaneous tissue, subcutaneous tissue. Striated and smooth tissue, muscle, mucous membranes, lymph vessels and nodes, organs and glands. Specific indications include:

Dermatology: Photocoagulation of cutaneous lesions including but not limited to the following general categories of lesions: vascular lesions (angiomas, hemangiomas, telangectasia), benign pigmented lesions (nevi, lentigines, chloasma, cafe au lait, tattoos (including but not limited to blue and black dark tattoo ink), verrucae, skin tags, keratoses, plaques, cutaneous lesions treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size)

General Surgery: Vaporization,coagulation, incision, excision, debulking and ablation of soft tissue in endoscopic or open surgeries

Gastroenterology: Vaporization, hemostasis,incision,excision,coagulation, ablation, and debulking soft tissue. Examples include: tissue ablation and hemostasis in the gastrointestinal tract, esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma, gastrointestinal hemostasis including varices, esophagitis, esophageal ulcer, mallory-weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions, gastrointestinal tissue ablation, benign and malignant neoplasm, polyps, ulcer, colitis, hemorrhoids

Gynecology: Vaporization, incision, coagulation of tissue associated with treatments of conditions such as endometriosis, cervical, vulvar and vaginal intraepithelial neoplasia, condyloma acuminata, uterinae septum, intrauterine adhesions and submuscosal fibroids.

Head/Neck/ENT: Incision, excision,coagulation,vaporization,ablation and vessel hemostasis

Neurosurgery: Incision,excision,coagulation,vaporization and ablation of peripheral soft tissue tumors

Plastic Surgery: Vaporization, coagulation, incision, excision, debulking and ablation of soft tissue in endoscopic and open procedures,

Spinal Surgery: Percutaneous lumbar diskectomy

Thoracic Surgery: Vaporization, coagulation, incision excision, debulking and ablation of soft tissue including lung tissue in thoracoscopic, bronchoscopic or open procedures.

Urology: Incision, excision,coagulation, vaporization and ablation of urological soft tissue.

Ophthalmology: Post vitrectomy endophotocoagulation of the retina

Technological Characteristics and Substantial Equivalence

The Ceralas G15 Laser System is a complete, self contained compact surgical laser system that utilizes a diode pumped neodymium-doped yttrium aluminum garnet (Nd:YAG) laser whose output is frequency doubled to produce radiation in the green visible spectrum at 532nm. Frequency doubling is achieved by the use of an intracavity KTP crystal. The laser employs a modular design which includes the laser crystal, a cooling module, continuous or pulsed operating modes, and front controls with a display panel. The laser system consists of models that range from .1 Watts to 15 Watts of output power. The Ceralas G15 Laser System is identical to the Ceralas G2 and G3 frequency doubled Nd:YAG Systems that have already received clearance. The delivery systems consist of an optical fiber and handpiece which is fitted with an SMA connector at the proximal end. The Ceralas G15 Laser System has the same intended use, similar principles of operation and similar technological characteristics as previously cleared predicate laser systems-Laserscope Aura/Lyra Series and the Cosmos Medical Technology COMPACT KTP Laser. The Ceralas G15 like its predicate devices is a solid state laser that emits a beam in the near infra red and the beam is frequency doubled to produce radiation in green visible spectrum. The wavelength of all these devices is 532nm. Each of these lasers offer continuous and pulsed modes of operation, operate in the contact and non-contact mode, use the same type of fiber delivery systems, and are air cooled. Thus the laser tissue interaction and the surgical performance of the Ceralas G15 and the predicate devices would be expected to be the same.

Any differences between the Ceralas G15 and the predicate devices such as the systems dimensions and weight do not raise new questions of safety and effectiveness.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2000

Carol J. Morello, VMD
Regulatory Affairs
Ceramoptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Re: K002296
Trade Name: Ceralas G15 532nm Frequency Doubled Nd:Yag Laser
Regulatory Class: II
Product Code: GEX
Dated: July 27, 2000
Received: July 28, 2000

Dear Dr. Morello:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002296

Device Name: Ceralas G15 532nm Frequency Doubled Nd:YAG Laser

Indications For Use:

See attached listing

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Mark N Milhauser

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 002296

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Intended Use

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Urology: Incision, excision,coagulation, vaporization and ablation of urological soft tissue.

Ophthalmology: Post vitrectomy endophotocoagulation of the retina and photocoagulation of ocular tissue.

Mark N Milhem 2002

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002296